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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,401	01/20/2006	Gary P. Cook	02181.0086U2	1909

23859 7590 10/07/2011

Ballard Spahr LLP
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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
10/07/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatentmail@ballardspahr.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,401	COOK, GARY P.	
	Examiner	Art Unit	
	SUSAN TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *10-14,16-18 and 37* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *10-14,16-18 and 37* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/GB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/02/10 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In view of the improper Markush language, it is not entirely clear whether the organic ion recited in claim 37 is to be present in the composition altogether or alternatively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-14, 16, 18 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamamoto et al. US 2003/0134800 A1.

Yamamoto teaches a controlled release composition comprising active substance or salt thereof, hydroxynaphthoic acid selected from 3-hydroxy-2-naphthoic aid, 1-hydroxy-2-naphthoic acid or salt thereof, and a lactic acid polymer (abstract; paragraphs 0013, 0109-0112, 0141-0142; and claims). Active substance is LH-RH derivative (paragraphs 0015-0018). Yamamoto discloses a number of methods that can be used to obtain the controlled release composition (see pages 8-15). The composition is in the form of microcapsule (paragraphs 0177, 0194, 0201).

The Examiner notes that the rejected claims are directed a product-by-process claims, and therefore, the patentability of a product does not depend on its method of production. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. If the product in the product-by-process claim is the same as or obvious from a product of the prior art,

the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

Claims 10-14, 16, 18 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orsolini et al. WO 02/058672 A2, in view of Yamamoto et al. US 2003/0134800 A1.

Orsolini teaches a sustained release microparticles formulation comprising a biodegradable polymer, a bioactive agent, a surfactant (organic ion), and an electrolyte (abstract; page 7, lines 6-15; and claims). The microparticles are prepared by providing an organic liquid phase comprising the biodegradable polymer and the bioactive agent, providing an aqueous phase comprising a surfactant, homogenizing the above organic and aqueous phases, and obtaining the microparticles (page 4, lines 17-30; page 6; and examples). Biodegradable polymer includes poly(D-L-lactide-co-glycolide) (page 8, lines 4-16). Surfactant includes anionic, non-ionic, and other surfactants (page 10, lines 8-29). Bioactive agents are disclosed in page 12, which also includes protein, peptide, polypeptide, LHRH, and the like.

Orsolini does not explicitly teach the claimed organic ion.

Yamamoto teaches a controlled release microcapsule comprising active substance or salt thereof, hydroxynaphthoic acid selected from 3-hydroxy-2-naphthoic aid, 1-hydroxy-2-naphthoic acid or salt thereof, and a lactic acid polymer (abstract; paragraphs 0013, 0109-0112, 0141-0142; and claims).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the microparticles of Orsolini to include the use of hydroxynaphthoic acid in view of the teachings of Yamamoto. This is because Yamamoto teaches the use of hydroxynaphthoic acid in a controlled release microcapsule is known in the art, because Yamamoto teaches that controlled release microcapsule made with hydroxynaphthoic acid exhibits advantageous results such as stable release speed for a long period of time by suppressing the initial excess release, and high content of active substance (paragraph 0008), and because Orsolini teaches the desirability for preparing a controlled release microparticles with slow release manner and very low burst (page 5, lines 21-31).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Orsolini et al. WO 02/058672 A2, in view of Yamamoto et al. and Bodmer et al. US 5,876,761.

Orsolini is relied upon for the reasons above. Orsolini does not expressly teach the claimed bioactive agent.

Bodmer teaches a microparticles composition comprising bioactive agent such as octreotide and salt thereof. See example 4; and claim 1. The composition also comprises pamoate (column 6, lines 37-40; and column 16, lines 5-7).

Thus, it would have been obvious to one of ordinary skill in the art to modify the microparticles composition of Orsolini to include the use of octreotide as a bioactive agent, because Bodmer teaches that octreotide is a useful somatostatin, because Bodmer teaches the incorporation of cotreotide in a biodegraxable biocompatible

polymeric carrier is known in the art (column 11, lines 42-49), and because Orsolini teaches the desirability for using somatrostatin in a microparticles composition.

Response to Arguments

Applicant's arguments filed 12/02/10 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615